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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/991,353

11/20/2001

Daniel Joseph Mollicone

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08/11/2004

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EXAMINER

MISKA, VIT W

ART UNIT

PAPER NUMBER

2841

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,353

Applicant(s)

MOLLICONE ET AL.

Examiner

Vit W. Miska

Art Unit

2841

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-12,14-16,18-22 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-12,14-16,18-22,24-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 5-12, 14, 18-22, 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Koyama et al. The reference discloses an apparatus for waking an individual including sensor 11 for measuring a parameter correlated to sleep level (pulse rate), and continually updating the same (col. 7, line 67), controller including the remaining elements in Fig. 1, capable of being set with the final wake up time (close to the final wake up time) by user interface input mechanism 20 (switches), the controller providing a stimulus 24 (audio, optical, etc. see col. 8, lines 15ff) at a time prior to the final wake up time (see col. 8, line 25), using the measured parameter to control the intensity of the stimulus (see col. 7, line 60 and col. 8 lines 30ff), to wake the individual gradually between the introduction of the stimulus and wake up time. With respect to claims 6, 8, 10 and 20, the reference further discloses an audio output means 27 for audibly announcing the sleep history (col. 9, line 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2, 15, 24, 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koyama et al, as applied to claims 1 and 14, above in view of Lidow.

A motion detector is not shown in Koyama et al as one of the sensors. Lidow, however, teaches the use of motion sensors 50 in conjunction with other sensors indicative of sleep level to produce an alarm signal stimulus at a selected wake up time in response to selected conditions. One skilled in the art having both references would thus have a suggestion of using a motion sensor in the Koyama et al device as a sensor indicative of sleep level, in place of or in addition to the pulse rate sensors disclosed, as shown in Lidow. The latter reference further teaches using the amplitude (col.2, line 37 and frequency of motion (col. 2, line 39) to determine sleep state.

3. Claims 3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koyama et al, as applied to claims 1 and 14, in view of Blackman. Koyama et al

suggests that several different stimuli may be produced in combination at col. 8, line 19. No separate intensity control means is disclosed therefor. In view of the suggestion of controlling the intensity of the stimulus at col. 7, line 62, one skilled in the art would have sufficient motivation to provide such control means in the event more than one stimulus is produced. Further, Blackman shows production of different wake up stimuli 136-142 with individual control thereof (col. 8, lines 50ff) to gradually increase the intensity of the stimuli. One skilled in the art having both references would thus have a teaching of independently controlling the intensity of each stimulus in Koyama et al, as done in the device of Blackman.

Response to Arguments

4. Applicant's arguments are directed at the added limitation in the independent claims and the 35USC 102(b) rejections over Koyama et al.

5. Applicant suggests that in Koyama et al the controller does not "control an intensity of the stimulus based on feedback which comprises the sensed values of the at least one parameter", as required in claims 1 and 14. However, Koyama et al specifically states at col. 7 that "the time and intensity of an awakening stimulus to be given to the user, is set on the basis of the sleep state consequences". The sleep state consequences refer to the state of the sleeping person as determined by the sensed

parameters, in this case the pulse rate. Further, following the description beginning with the quoted paragraph through col. 8, line 61, it is clearly set forth that the intensity of the stimulus is based on feedback of the sensed parameters pertaining to the sleep state. For example, if the person is in the termination of REM sleep period (col.8, lines 11ff), the stimulus may have an initial level that is lower (line 22) and is then gradually increased, whereas if the person is in the awakening period when the alarm introduction alarm time T_p arrives, the awakening stimulus is strong (line 30). These examples are sufficient to meet the limitations of claim 1 of "controlling the intensity of the stimulus base on feedback....of the at least one parameter",. The claim does not specify in what manner and at which time periods the intensity is controlled, the details of which perhaps have been read into the claim by applicant.

6. A further example of intensity control of the awakening stimulus based on the sensed parameters is given at col. 8, lines 46ff. In this condition, when the heart rate falls decreases for a period of time after the first stimulus is applied, another stronger stimulus is applied to wake up the individual.

7. With respect to claims 12 and 22, these claims contain the additional limitation of the controller capable "to continuously control an intensity of the stimulus over a period of time..." in addition to the new limitation noted above with respect to claim 1. Applicant argues that in Komiya et al the intensity control in not performed continuously, but at 1 minute intervals as set forth at col. 8, line 1. Although applicant's observation is true

with respect to Komiya et al, it is noted that that reliance on the term “continuously” to distinguish over Komiya et al is not sound. Applicant’s specification at page 13, lines 10-12 states “the parameter measured by the detection system may be input to the controller at least once, or continuously at a particular high frequency.” Further, at page 27, lines 5ff: “biofeedback detection subsystem 13 begins continually detecting the amplitude and frequency...” and lines 16 ff: the intensity of the introduced stimulus...which the controller 12 continually calculates and updates...”. It is clear that the term “continuously” as employed in the claims refers to the actual physical sequence of events more aptly described as “continually” in the specification. The measurement of the parameters described in the specification, i.e. motion, heart rate, etc. requires a finite period of time, and thus the signals corresponding thereto which are received by the controller occur at periodic finite intervals of time, as noted in the specification. For example, the measurement of heart rate requires a period of time on the order of several seconds. Therefore, the term “continually” or “continuously”, refers to the primary definition of the former term, or a repeated pattern of events. The measurement of the heart rate at intervals of 1 minute for the period of time from T_p to wake up time in Komiya et al thus corresponds to the limitation in applicant’s claims of continuously controlling the intensity of the stimulus based on the sensed values of the at least one parameter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vit W. Miska whose telephone number is 571-272-2108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.C. Patel can be reached on 571-272-2098. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VM
8/5/2004



Vit Miska
Primary Examiner